Dkt. 44657-AAA-PCT-US/JPW/MPL

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Joseph R. Berger

Serial No. : Not Yet Known

Filed : Herewith

For : A METHOD FOR AMELIORATING MUSCLE WEAKNESS/WASTING IN A PATIENT INFECTED WITH HUMAN IMMUNODEFICIENCY VIRUS-TYPE 1

1185 Avenue of the Americas
New York, New York 10036
January 18, 2002

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

PRELIMINARY AMENDMENT AND INFORMATION DISCLOSURE STATEMENT DIRECTED TO THE ACCOMPANYING CONTINUATION APPLICATION UNDER 37 C.F.R 1.53(b)

Applicant requests that the following amendments be made in the above-identified application.

In the Specification:

Page 1, line 5, before the paragraph "Technical Field" please insert the following as a separate paragraph:

--This application is a continuation of U.S. Serial No. 09/469,817, filed December 22, 1999, now allowed, which is a continuation of application U.S. Serial No. 08/244,988, filed June 22, 1995, now U.S. Patent No. 6,090,799, issued July 18, 2000, which is a §371 of PCT International Application No PCT/US93/10063, filed 20 October, 1993,

claiming priority of U.S. Serial No. 07/963,469, filed October 20, 1992.--

In the Claims:

Please cancel claims 1-42 without prejudice to applicant's right to pursue the subject matter of these claims in a subsequent application.

Please add new claims 43-58 as follows:

--43. (New) A composition comprising oxandrolone in an amount effective to attenuate the rate of muscle mass loss for the amelioration of myopathy and muscle weakness in a patient infected with Type-I human immunodeficiency virus.--

--44. (New) The composition of claim 43 and a pharmaceutically acceptable carrier.--

--45. (New) The composition of claim 44 for percutaneous administration.--

--46. (New) The composition of claim 44 for intravenous administration.--

--47. (New) The composition of claim 44 for intramuscular administration.--

--48. (New) The composition of claim 44 for sublingual administration.--

--49. (New) The composition of claim 44 for transdermal administration.--

--50. (New) The composition of claim 44 for oral administration.--

--51. (New) The composition of claim 44 for administration over a time period in the range of about 2 weeks to about 6 months.--

--52. (New) The composition of claim 51 wherein the effective amount provides a daily dosage in the range of about 2.5 to about 30 milligrams oxandrolone.--

--53. (New) The composition of claim 52 wherein the effective amount provides a daily dosage of about 7.5 milligrams oxandrolone.--

--54. (New) The composition of claim 52 wherein the effective amount provides a daily dosage of about 15 milligrams oxandrolone.--

--55. (New) The composition of claim 52 wherein the effective amount provides a unit dose of about 1 to about 5 milligrams oxandrolone and is administered 3 times per day at about equally spaced intervals.--

--56. (New)A composition according to claim 52 comprising oxandrolone for the amelioration of myopathy and muscle weakness in a patient infected with a Type-1 human immunodeficiency virus and a pharmaceutically acceptable carrier such that the composition is an oral composition and is appropriate for administration for a time period in the range of about 2 weeks to about 6 months.--

--57. (New)The composition of claim 56 in the form of a tablet.--

--58. (New)A composition for the amelioration of myopathy and muscle weakness comprising oxandrolone in an amount effective to attenuate the rate of muscle mass loss in a patient infected with a Type-I human immunodeficiency virus.--

REMARKS

The subject application is a continuation of U.S. Serial No. 09/469,817 filed December 22, 1999. An Official Notice of Allowance was issued on August 24, 2001 in connection with U.S. Serial No. 09/469,817. The Notice of Allowance indicated that the Issue Fee was due on November 26, 2001. The Issue Fee was paid in a timely manner, but U.S. Serial No. 09/469,817 has not yet issued as a U.S. patent as of the filing of the subject application. Accordingly, U.S. Serial No. 09/469,817 is pending and the subject application is co-pending therewith for purposes

of 35 U.S.C. §120.

Applicant maintains that the amendment to the specification presents no issue of new matter and is fully supported by the specification. Applicant has amended the specification to incorporate a reference to the parent application, U.S. Serial No. 09/469,817, filed December 22, 1999, in accordance with 35 U.S.C. §120, and to provide an updated status of the prior related applications.

By this Preliminary Amendment, claims 1-42 have been canceled without prejudice to Applicant's right to pursue the subject matter of these claims in a subsequent application and new claims 43-58 have been added. Accordingly, upon entry of this Amendment, claims 43-58 will be pending and under examination.

Support for new claim 43 may be found throughout the specification and inter alia, on page 4, lines 25-28, and in claim 15 as originally filed. Support for new claim 44 may be found inter alia, on page 5, lines 20-22, and in claim 15 as originally filed.

Support for new claims 45, 46, 47, 48, 49 and 50 may be found inter alia on page 6, lines 29-31, and in claims 20 through 25 as originally filed. Support for the new claim 51 may be found inter alia on page 6, lines 8-9, and in claim 27 as originally filed.

Support for new claim 52 may be found inter alia on page 5, lines

27-32, and claim 16 as originally filed. Support for new claim 53 may be found inter alia on page 6, lines 32 - 34, and claim 17 as originally filed. Support for new claim 54 may be found inter alia on page 5, lines 30-31, and in claim 18 as originally filed.

Support for new claim 55 may be found inter alia on page 7, lines 6 - 8, and in claim 19 as originally filed. Support for new claim 56 may be found inter alia on page 6, lines 7 - 14, and in claim 28 as originally filed. Support for new claim 57 may be found inter alia on page 7, lines 9-14, and in claim 26 as originally filed. Support for new claim 58 may be found inter alia on page 3, lines 6-10.

Accordingly, applicant respectfully requests that the amendments be entered.

Information Disclosure Statement

Applicant would like to direct the Examiner's attention to the following references which are listed on the attached Form PTO-1449 (**Exhibit 1**) and which were previously cited in connection with the prosecution of U.S. Serial Number 09/469,817 from which the subject application claims benefit under 35 U.S.C. §120. According to 37 C.F.R. §1.98(d), copies of patents or publications that were previously cited by, or submitted to, the Office in connection with such prior applications need not accompany the Information Disclosure Statement. Accordingly, copies of the following references are not attached to this

Information Disclosure Statement:

1. European Patent Specification, Publication No. 0 222 385 B1, published February 3, 1993;

2. Endo, Chemical Abstracts, Vol. 73: 95098g, 1970;

3. O'Shea, et al., Chemical Abstracts, Vol. 74: 75106a, 1971;

4. Physicians' Desk Reference (1988), 42nd Edition, cover page and pages 1975-1976;

5. Aroonsakul, Chemical Abstracts, Vol. 115: 151902q, 1988;

6. Boris, et al.,Chemical Abstracts, Vol. 74: 72305d, 1971;

7. Chicago Tribune, September 20, 1991, North Sports Final edition, Business Section, page 1;

8. Kopera, H. Acta Endocrinologica 1985, Supplementum 271, pp. 11-18;

9. Lone, et al., Chemical Abstracts, Vol. 107: 174950c, 1987;

10. Martindale, The Extra Pharmacopoeia, The Pharmaceutical Press, London, Reynolds, et al., Eds., p.1430 (1982); and

11. PR Newswire, 0828P8715, August 28, 1991 "Gynex obtains international rights to drug to treat for growth disorders,

AIDS".

No fee, other than the enclosed fee of $370.00 for filing the subject application, is deemed necessary in connection with the filing of this Preliminary Amendment and Information Disclosure Statement. However, if an additional fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

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Respectfully submitted,

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